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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/800,323

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Jessica G. Chiu

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BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP
1279 OAKMEAD PARKWAY
SUNNYVALE, CA 94085-4040

EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/800,323	Applicant(s) CHIU ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-68 and 79-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-68, 79-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/6/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 61, 63, 68, 79, 80, 82, 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolinsky (US Patent No. 4,636,195). Wolinsky discloses a method comprising: advancing a cannula percutaneously through a blood vessel to a region of interest (fig. 3), the cannula having a proximal end (Fig. 1, upstream of 11-13), a distal end (2), and an exterior surface at or adjacent the distal end of the cannula axially coupled to a balloon (the examiner is interpreting the balloon to be the balloon labeled 9, which is adjacent the distal end), inflating the balloon from a first diameter to a different second diameter that is at least equivalent to an inner diameter of a blood vessel to occlude the blood vessel at the region of interest wherein inflating includes inflating the balloon for a first period of time to occlude the blood vessel for the first period of time (col. 2, lines 58-68 disclose that balloon 9 is inflated and occludes the vessel. Please note that Applicant has not claimed that the catheter has only one balloon along the shaft); then infusing a treatment agent to the region of interest distal to the balloon during the occlusion of the blood vessel (col. 3, lines 11-25 disclose that a treatment agent is infused out of lumen 7 which is distal to balloon 9 and which is infused while the balloons are inflated); then perfusing blood and the treatment agent

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wherein perfusing comprises allowing blood to flow from a location in the blood vessel proximal to the balloon to the region of interest distal to the balloon, wherein perfusing comprises perfusing immediately after the first period of time (col. 3, lines 31-44 disclose that the balloons are deflated after infusing the agent distal to balloon 9 and that this is done to allow blood to flow between the infusion repetitions).

In reference to claim 63, Wolinsky discloses that perfusing includes deflating the balloon for a second period of time and at least one more repetition of inflating, infusing and deflating (col. 3, lines 31-44).

In reference to claim 68, Wolinsky discloses that the inflating includes increasing an axial length of the balloon; and maintaining the inflation pressure on the inner diameter of the blood vessel (Figs. 1 and 3; col. 3, lines 31-44).

In reference to claims 79 and 80, Wolinsky discloses that perfusing comprises perfusing the blood vessel coupled by human vasculature to a human having a beating heart (Figs. 1-3).

In reference to claim 82, Wolinsky discloses that perfusing comprises perfusing a blood flow from a location in the blood vessel proximal to the balloon, to a location in the region of interest distal to the balloon (figs. 1 and 3; col. 3, lines 31-44).

In reference to claim 84, Wolinsky discloses that perfusing comprises perfusing blood or the treatment agent (col. 3, lines 31-44).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 62 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (US Patent No. 4,636,195) in view of Sahota (US Patent No. 5,147,377). Wolinsky discloses the device substantially as claimed except for the perfusing between the proximal and distal ends of the balloon occurring due to blood entering and exit a lumen of the catheter via holes in the surface of the catheter on both the proximal and distal sides of the balloon. Sahota, however, discloses a similar device (Figs. 8 and 10) in which there are perfusion holes (54 and 56) on both the proximal and distal sides of the balloon. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Wolinsky's device such that it included perfusion holes on either side of the balloon, as taught by Sahota, in order to provide a device that can permit blood perfusion while the balloon is inflated, thus allowing the tissue to get proper blood flow during the balloon's inflation.

Claims 64-66 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (US Patent No. 4,636,195) in view of Sahota (US Patent No. 5,147,377). Wolinsky discloses the device substantially as claimed except for a guidewire within the catheter being retractable to either open or close the perfusion holes. Sahota, however, discloses a similar device in which a guidewire (being interpreted as element 10 in Figs. 8 and 10) resides within the catheter lumen further discloses retracting back a guidewire disposed through a guidewire lumen extending from the proximal end to the distal end of the cannula and exiting an opening in the cannula distal to a balloon, for a first period of time; wherein retracting includes retracting a distal end of the guidewire from a location distal to at least one hole from the guidewire lumen through the exterior surface of the cannula and proximal to the balloon to a location proximal to the at least one hole to cause perfusion through the at least one hole (Fig. 10). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Wolinsky's device with the guidewire, as taught by Sahota, in order to provide a device that enables selective perfusion through the perfusion holes. In reference to claims 65 and 66 and 83, please see Figs. 8 and 10.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (US Patent No. 4,636,195) in view of Alt (US Patent No. 6,805,860). Wolinsky discloses the method substantially as claimed except for the infusing of progenitor cells. Alt, however, discloses a method of infusing progenitor cells (Fig. 1 and col. 13, lines

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27-31). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Wolinsky with the step of infusing progenitor cells, as taught by Alt, in order to provide a method of treating a wider spectrum of diseases.

Response to Arguments

Applicant's arguments with respect to claims 61-68 and 79-84 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

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